

## REMARKS

Claims 1-62 are in the present application.

In order to advance prosecution and further clarify the present invention, Applicants have amended Claims 1-3, 7-9, 11-14, 17-18, 20-24, 30-33, 39, 41-42, 44-45, 47-48, 50-51, 53-55, and 57-58 and added new claims 59-62. Support for these amendments and new claims can be found in the Specification.

The Examiner has rejected Claims 1, 4, 7, 9, 10, 20, 23, 24, 28 and 29 under 35 USC Section 102(b) as allegedly anticipated by Nakahara et al. Claims 1, 3, 4, 5, 9-11, 13, 15, 18-20, 22, 24, 25, 28-30, 32, 35, 37 and 38 have been rejected under 35 USC Section 102(b) as allegedly anticipated by Brace. Claims 1, 3, 4, 6, 9, 10, 20, 22, 24, 26, 28 and 29 have been rejected under 35 USC Section 102(b) as allegedly anticipated by Perks et al.

Claims 2, 7, 21 and 23 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Fraatz et al and Nakahara et al. Claims 8 and 27 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Kruezer. Claims 39-41 and 45-47 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Carr et al. Claims 51-58 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Berndt et al.

Claims 5, 11, 13, 15, 18, 19, 25, 30, 32, 34, 37 and 38 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Waters and Brace. Claims 12, 14, 31 and 33 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Waters, Brace, Fraatz et al and Nakahara et al. Claims 17 and 36 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Waters, Brace and Kruezer. Claims 42-44 and 48-50 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Perks et al in view of Waters, Brace and Carr et al. None of the cited prior art anticipates, or suggests the claimed invention.

The present invention is directed to systems and methods for detecting the growth of microorganisms in a sample in a container by monitoring pressure or the concentration of a gas related to microorganism metabolism in the container.

Nakahara et al, Brace and Perks et al do not anticipate the claimed invention as amended. In particular, Nakahara et al do not teach microorganism growth, they do not provide any teaching regarding a laser, and do not mention CO<sub>2</sub>, O<sub>2</sub>, NH<sub>3</sub>, CH<sub>4</sub> or H<sub>2</sub>S.

Brace does not contain the elements of the claimed invention as amended. Brace is specific only for the measurement of pressure, but by teaching a very specific method (see col. 2, lines 15-40) that is totally distinct from the claimed pressure method in the present application. Applicants teach a method involving the width of the absorption peak as a measurement of pressure, as temperature is held constant. (p. 17 of the specification, para [0065] and [0066]). In addition, as Applicants use a laser, which emits light at a single wavelength, not a wavelength (or frequency) band, which is part of the Examiner's allegations, and which is taught in Brace (see, for example, col. 2, ln 2, 28).

With respect to Perks et al, this reference is specific for ID (identification) of microorganisms not detection of growth (see p. 3, lines 18-21). The present invention as claimed is directed to detection of growth of microorganisms. Second, the incubation period in Perks et al is for a predetermined length of time (see p. 3, line 27-p.4, line 2). In the present application, there is no claim of predetermined incubation period. It will be understood by skilled microbiologists that the time is whatever it takes until growth is detected. In Perks et al, each sample is incubated in a plurality of vials or bottles, each containing a specific carbon source, the actual source of CO<sub>2</sub> to be detected. A pattern of growth/no growth is determined, and then compared to the patterns given by known organisms. In this way, an ID of the organism can be determined. There is no teaching of a laser in Perks et al. Perks et al also teach a wavelength band (see p. 7, line 25 to p. 8, line 3), which is not how a laser (single wavelength) operates.

Although the claims have been rejected as anticipated under 35 USC Section 102(b) on the disclosure of each of Nakahara et al, Brace and Perks et al, it is axiomatic that anticipation under Section 102 requires that the prior art reference disclose every element of the claim. In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986). Thus there must be no differences between the subject matter of the claim and the disclosure of the prior art reference. Stated in another way, the reference must contain within its four corners adequate directions to practice the invention. The corollary of this rule is equally applicable. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986).

Here it is clear that the rejected claims distinctly differ from Nakahara et al, Brace and Perks et al. Clearly, Kloster Speedsteel shows that the cited prior art falls far short of the statutory standard of 35 USC Section 102(b). The rejected claims are not anticipated by Nakahara et al, Brace and Perks et al. Withdrawal of the instant rejection under Section 102 is therefore respectfully requested.

Regarding the rejections under Section 103(a):

1) Perks et al in view of Fraatz and Nakahara et al

Perks et al teach a method for determining the ID of essentially bacteria by using the measurement of CO<sub>2</sub>, using IR absorption. But, it does not teach growth detection, or the use of a laser. Fraatz teaches the use of a fluorescent sensor for CO<sub>2</sub> inside of the sample bottle. It does not teach IR spectroscopy for CO<sub>2</sub> detection, which does not use a sensor inside of the bottle. In terms of the other gasses, Fraatz suggests that separate sensors inside the bottle can be used, but it still does not teach IR spectroscopy from outside the bottle to do this. Nakahara et al teach a method for spectroscopic determination of NO, NO<sub>2</sub>, and SO<sub>2</sub>, but do not teach the use of a laser, nor the ability to detect CO<sub>2</sub>, or O<sub>2</sub>, or NH<sub>3</sub>, or H<sub>2</sub>S. Thus, Fraatz cannot be logically combined with the other two references to end up with the claimed invention, as it is specific for sensors inside the sample bottle, and combining Perks et al and Nakahara et al with Fraatz would not lead to the claims of the present invention (including use of a laser; measurement of CO<sub>2</sub>, O<sub>2</sub>, H<sub>2</sub>S, NH<sub>3</sub>, and measurement of growth as opposed to bacterial ID).

2) Perks et al in view of Kruezer

Perks et al has already been discussed. Kruezer uses the modulation of the frequency of the input IR beam from a laser. This impinges into a gas sample contained in a metal container that has a very specific structure (see col. 2). The modulation causes a pressure change, which in turn modulates the capacitance of a detector. Thus, the signals are not absorption of IR input light, but of electrical capacitance changes. This is fundamentally different from the claims of the present invention, and even when considered with Perks et al, will not provide teachings which will achieve the claimed invention. Thus, it would not be obvious to employ a laser light source from Kreuzer as the method of use is fundamentally different.

3) Perks et al in view of Carr

Carr uses a laser to measure the deformation of the septum of each sample container. It does not measure CO<sub>2</sub> by IR absorption. Thus, Carr teaches away from IR absorption. In Carr, the sample vials have to have a specific construction (see Fig. 3). The Examiner chooses not to discuss the real teaching of Carr, the use of the laser to measure the pressure changes in the sample vials by measuring the deformations of the septa. Instead, the Examiner only notes that Carr does teach that one can interrogate a plurality of sample vials using a light source and detector that is movable. However,

as stated above, the "detector" and "light source" simply measure the deformation in the sample vials' septa as a measure of pressure changes. Obviously, this is different than the present invention. A combination of the teachings of Perks et al and Carr cannot achieve the claimed invention. One would simply obtain an ID system that determines pressure changes as a measurement of conversion of substrates to CO<sub>2</sub>, which is not the present invention as claimed.

4) Perks et al in view of Berndt

Berndt specifically teaches a turntable for holding the sample vials and rotating them to a reading station. The sample vials have a sensor inside of the vial (see col 4, lines 14-16, and Fig 2). Thus, if one were to combine Berndt with Perks et al, one could end up with an apparatus for ID that mounts the sample vials on a turntable, but uses a sensor for CO<sub>2</sub> inside of the vials instead of the IR measurement of Perks et al, or one could end up with an ID apparatus that mounts the vials on a turntable (like Berndt), and moves them to a reading station where IR is read using a light source and detector (like Perks et al). This version is, in fact, Perks et al. There is no need to combine Berndt with Perks et al to get this model, as this is precisely what Perks et al teach. There is no laser in Perks et al and Berndt. These references do not teach or suggest the claimed invention.

5) Perks in view of Waters and Brace

Waters is yet another method for measuring growth of microorganisms in a sample by measuring the pressure change as the microorganisms respire and produce CO<sub>2</sub>. It, however, is a very specific pressure sensor, consisting of a flexible membrane in the seal portion of a sample vial or container(see Figs 1, 2, 3 and 5). It does not use IR absorption spectroscopy as a measure of pressure, as the present invention does.

Brace has already been discussed above. One of ordinary skill in the art would not be able to combine Waters with Brace as they are based on totally different methods of analysis. And then combining them with Perks et al would also not make any scientific sense.

Accordingly, the claimed invention is neither taught nor suggested by the cited prior art references. Therefore, withdrawal of the present rejections under 35 USC Section 103 is respectfully requested.

Thus in view of the above remarks, it is believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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